



UNITED STATES DEPARTMENT OF COMMERCE  
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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
09/776,044	02/26/97	BYWATER	M 1614-178P

002292 HM12/1025  
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EXAMINER	
HOLLERAN, A	
ART UNIT	PAPER NUMBER
1642	20

DATE MAILED:

10/25/00

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

### ADVISORY ACTION

☒ THE PERIOD FOR RESPONSE:

- a) ☒ is extended to run 4 months ~~or continues to run~~ from the date of the final rejection
- b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☒ Applicant's response to the final rejection, filed Oct. 10, 2000 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☒ The proposed amendments to the claim and/or specification will not be entered and the final rejection stands because:

- a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.
- b. ☒ They raise new issues that would require further consideration and/or search. (See Note).
- c. ☐ They raise the issue of new matter. (See Note).
- d. ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
- e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: See attached.

2. ☐ Newly proposed or amended claims \_\_\_\_\_ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☒ Upon the filing an appeal, the proposed amendment ☐ will be entered ☒ will not be entered and the status of the claims will be as follows:

Claims allowed: \_\_\_\_\_  
Claims objected to: \_\_\_\_\_  
Claims rejected: 1-11, 14 and 15

However;

☒ Applicant's response has overcome the following rejection(s): If entered, the amendment would overcome the rejection of claims 1-11, 14 & 15 under 35 U.S.C. 112, 1st (New matter)

4. ☒ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because See attached.

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☐ Other

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**DETAILED ACTION**

**Item 1b.**

The proposed amendment to the claims raise new issues under 35 U.S.C. 112, 2nd paragraph for lack of antecedent basis of "the parts", and new issues under 35 U.S.C. 112, first paragraph for scope of enablement because the specification does not enable one of skill in the art to practice the claimed methods commensurate in scope with that of claims drawn to methods comprising determining the nucleotide sequence of biologically functional domains of p53; and for new matter because the specification does not provide support for a classification system based upon the sequence alone.

**Item 4.**

A. If entered, the amendment would overcome the present grounds of rejection of claims 1-11, 14 and 15 under 35 U.S.C. 112, first paragraph. However, it is noted that in Applicant's arguments, this rejection was characterized as an enablement rejection. For the purposes of clarification of the record, this rejection is a rejection under 35 U.S.C. 112, first paragraph because of new matter and is not an enablement rejection.

The rejection of claims 1-11, 14 and 15 under 35 U.S.C. 112, first paragraph is maintained for the reasons of record.

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B. The rejection of 15 under 35 U.S.C. 102(e) as being anticipated by Diamandis et al (U.S. Patent No. 5,552,283) is maintained for the reasons of record.

With respect to amended claim 15, Applicant's arguments that the amendment overcomes the art of record have been considered but not found persuasive. Applicant specifically points to the step "b" of claim 15 in which the entire sequence determined in step is analyzed for the presence of mutations. Applicant asserts that as currently recited the claims read on analyzing the entire coding region of a p53 nucleic acid which Applicant asserts is not taught by Diamandis et al. This argument is not found persuasive because the nucleotide sequence determined in step "a" is a nucleotide sequence which encodes a part of a p53 protein. Thus, Applicant is arguing for a limitation that is not present in the claims.

C. The rejection of Claims 1-10 and 14 under 35 U.S.C. 103(a) as being unpatentable over Elledge et al. (Breast Cancer Res. Treat. 27: 95-102, 1993) and of Callahan (J. Natl. Cancer Institute, 84: 826-827, 1992) in view of Diamandis et al (U.S. Patent No. 5,552,283) is maintained for the reasons of record. Applicant presents no arguments why amended claims 1-10 and 14 are not obvious over the art of record.

D. Because the amendment of claims will not be entered, the denial of priority under 35 U.S.C. 119(a-e) is maintained.

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892.

Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

ALH

Anne L. Holleran  
Patent Examiner  
October 23, 2000

ac

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